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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,108	06/18/2001	Jane Dixon	3875-4138US	6832

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EXAMINER

PAK, MICHAEL D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,108

Applicant(s)

DIXON ET AL.

Examiner

Michael Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10-14,21,32,35,36,43,44 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10-14,21,32,35,36,43,44 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Amendment filed 2 August 2005 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 2 August 2005 have been fully considered but they are not found persuasive.
4. The Declaration of Robert Krafte under 37 CFR 1.132 filed April 7, 2005 is insufficient to overcome the rejection of claims 1, 4-7, 10-14, 21, 32, 35-36, 43-44 and 46-49 based upon 35 USC 101 as set forth in the last Office action.

The arguments regarding the declarataion is set forth in the rejection of 35 USC 101 below.

Claim Rejections - 35 USC § 101 and 35 USC § 112

5. Claims 1, 4-7, 10-14, 21, 32, 35-36, 43-44 and 46-49 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The reason for the rejection has been set forth in the previous office action.

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Applicants argue that specification on page 16-17 teach that potassium channel are associated with various diseases. However, the specific potassium channels claimed are not associated with the specific diseases recited but rather other family members of potassium channels which are different from the claimed potassium channels and the specific potassium channel each are associated with a specific disease which is different from other potassium channel associated diseases.

Applicants argue that The Declaration of Douglas Krafte provides supports utility of the claimed invention. The Declaration of Douglas Krafte state that Elk and eag channels claimed are related to Erg channels and thus have utility for drug discovery. However, the Erg channels have specific nexus to the diseases. The specificity of elk and eag channels to specific ligands does not provide a model for Erg channels drug discovery.

Applicants argue in the Declaration of Douglas Krafte that therapeutic agents can be discovered without knowledge of expression of channels in specific tissues. However, further substantial experimentation would be required and thus substantial utility is not met.

Thus the corresponding asserted utilities are essentially methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use such as identifying a disease with the mutation in the claimed gene

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sequence. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed polynucleotide or its encoded polypeptide, further experimentation is necessary to attribute a utility to the claimed invention. See *Brenner v. Manson*, 383 U.S. 519, 535B36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

6. Claims 11, 4-7, 10-14, 21, 32, 35-36, 43-44 and 46-49 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 12-14 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-14 and 21 recite terms "stringent hybridization", "specifically hybridizes" or "moderately stringent hybridization" which are relative terms whose conditions are not defined and the metes and bounds of the terms not clear.

Priority

8. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1, 4-7, 10-14, 21, 32, 35-36, 43-44 and 46-49 of this application for the reasons provided above. See MPEP 706.02.

Claim Rejections - 35 USC § 102

9. Claims 1, 4-7, 10-14, 21, 32, 35-36, 43-44 and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipate by Curtis et al. (US 6,518,398).

Curtis et al. disclose nucleic acid encoding SEQ ID NO:36 which has 100% amino acid sequence identity with the claimed SEQ ID NO:2 (figure 11, columns 2-6, 10-23, 32-38 and 42-47). Curtis et al. disclose vectors and isolated host cells comprising the nucleic acid (columns 32-38). Curtis et al. disclose screening assay using the host cell (columns 32-38 and 42-47).

Since the nucleic acid of Curtis et al. has regions 100% identity with the claimed nucleic acid molecule the nucleic acid of Curtis et al. will hybridize at the highest stringent conditions.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Michael Pak
Primary Patent Examiner
Art Unit 1646
12 October 2004